DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 4, 2015

Acumed Medical, LTD.
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907-1659

Re: K133789
Trade/Device Name: Dolphin Neurostim OTC
Regulation Number: 21 CFR 890.5890
Regulation Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulatory Class: Class II
Product Code: NUH
Dated: January 31, 2015
Received: February 4, 2015

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133789

Device Name
Dolphin Neurostim™ OT C

Indications for Use *(Describe)*
The Dolphin Neurostim™ OT C is indicated for temporary relief of pain associated with sore and aching muscles in the back, arms, and legs due to strain from exercise or normal household and work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

(per 21 CFR 807.92)

3 March 2015

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Proprietary Name:	Dolphin Neurostim tm OTC
Common Name	TENS device
Device Classification Name	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Classification Number:	21 CFR 882.5890
Product Code	NUH
Reviewing Group	Neurological Therapeutic Devices
Device Classification	Class II
Establishment registration No.	new submission
Predicate Device	Painmaster MCT Patch K130114 and TENS Pro 900 K023726

Device Description

The Dolphin Neurostim OTC is designed to perform transcutaneous electrical nerve stimulation (TENS) and as such is a Class II device, having **Regulation Number**: 882.5890 and **Classification Number**: NUH. The Dolphin Neurostim™ OTC (DNS) is a handheld, battery powered (9V) Transcutaneous Electrical Nerve Stimulators (TENS), specifically designed for the temporary relief of muscular pain. It combines the electrical characteristics of TENS with point stimulation delivered through a metal probe tip (cathode or anode). There is a metal ground on the device and an ancillary wrist strap that plugs into the device (cathode or anode). The device has two modes of operation. In search mode it locates points of low resistance in a predetermined area. In treatment mode it applies a low-frequency (2.4-3.0 Hz) Direct Current to the skin.

Indications For Use

The Dolphin Neurostim™ OTC is indicated for temporary relief of pain associated with sore and aching muscles in the back, arms, and legs due to strain from exercise or normal household and work activities.

Intended Use

The **intended use** of the Dolphin Neurostim OTC is to deliver transcutaneous electrical nerve stimulation (TENS).

5. 510(k) Summary

(per 21 CFR 807.92)

Substantial Equivalence

ACUMED Medical has determined that the Dolphin Neurostim, OTC is substantially equivalent to the performance of a predicate Device. The differences between these systems are incidental and not significant. Both devices use similar technological characteristics and principles.

- Both devices deliver TENS waveform to patients.
- both devices are sold over the counter.

The Dolphin Neurostim tm is an over the counter version to its prescription device counterpart that has been sold in the US for 20 years. The Dolphin Neurostim has been sold over the counter in other countries for over 20 years for a total of 60,000 units.

Comparable Parameter	**Dolphin Neurostim K133789**	**Painmaster MCT Patch, K 130114**
Transcutaneous Electrical Nerve Stimulator for Pain Relief	Yes	Yes
Intended Use	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms or legs due to strain from normal exercise or normal household and work activities.	The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities. This intended use is a subset of the intended use for the device when it was cleared for prescription use, and is also identical to that of other OTC cleared TENS devices.
technological characteristics	Stimulation current delivered to electrodes applied to skin.	Stimulation current delivered to electrodes applied to skin.
Material	Plastic case with electrodes constructed of metal.	Plastic case with electrodes constructed of metal.
output waveform design	single non-programmable milliamp mode, delivering a pulsed biphasic waveform that provides electrical stimulation to the body to relieve pain.	single non-programmable microcurrent mode, delivering a pulsed monophasic waveform that provides electrical stimulation to the body to relieve pain.
maximum average power density watts/sq cm	0.116	Below safety limit
maximum current density amps/sq cm	0.21	Below safety limit
maximum charge per pulse coulombs	0.00044	Below safety limit

Testing

The Dolphin Neurostim™, OTC has benefited from design, development, testing and production procedures that conform to Quality Systems. Testing has confirmed this device meets its product specification. A series of factory tests are conducted to verify the intended signals are accurate and can maintain a calibrated energy pattern over its useful life. Testing has established this device is substantially equivalent to the predicates.

Conclusion

There are no substantial differences between the Dolphin Neurostim OTC defined in this 510(k) submission and the stated predicate device.